UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/879,827	06/20/97	JOFURU K	023070067210

HM21/0624

TOWNSEND AND TOWNSEND AND CREW LLP
TWO EMBARCADERO CENTER, 8TH FLOOR
SAN FRANCISCO CA 94111-3834

EXAMINER	
MOSHER, M	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 06/24/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/879,827	Applicant(s) Jofuku et al
	Examiner Mary Mosher	Group Art Unit 1643

☒ Responsive to communication(s) filed on *2/2/98, 3/2/98, 6/1/98* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-44* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-44* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Priority

The first sentence of the specification incorrectly identifies this application as a continuation, rather than a continuation-in-part, of application 08/700,152. Correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-44 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of copending Application No. 08/700,152. Although the conflicting claims are not identical in scope, they are not patentably distinct from each other because the instant claims encompass the subject matter claimed (in more narrow form) in the '153 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-44 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-59 of copending Application No. 08/912,272. Although the conflicting claims are not identical, they are not patentably distinct from each other because they overlap in scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

Claims 1-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-44 require "an ADC nucleic acid". In order to understand the metes and bounds of "an ADC nucleic acid", the Examiner has looked to the specification for definition. The term is defined at several locations:

Page 5 lines 7-10: "a subsequence or polynucleotide sequence of a gene which, encodes an polypeptide (sic) containing an AP2 domain and when present in a transgenic plant, can be used to modulate seed properties in seed produced by the plant".

Page 5 lines 18-20: "ADC polynucleotides are defined by their ability to hybridize under defined conditions to the exemplified nulciec (sic) acids or PCR products derived from them."

Page 5 lines 25-31: "ADC polypeptides, which are distinguished by the presence of one or more of a 56-58 amino acid repeated motif, referred to here as the 'AP2 domain'. The amino acid

sequence of an exemplary AP2 polypeptide is shown in Jofuku et al, supra. One of skill will recognize that in light of the present disclosure various modifications (e.g. substitutions, additions, and deletions) can be made to the sequences shown there without substantially affecting its function. These variations are specifically covered by the terms ADC polypeptide or ADC polynucleotide"

So, an AP2 domain is defined in the specification as having "one or more of a 56-58 amino acid repeated domain", or any sequence modified by substitution, addition, or deletion which does not substantially affect the function of modulation of seed properties. Therefore the definition of an AP2 domain reasonably encompasses any sequence which affects seed properties. Furthermore, the specification provides an inconsistent definition of an ADC nucleic acid as one which hybridizes under (unspecified) defined conditions to the exemplified (but unspecified) nucleic acids or CPR products (unspecified) derived from them. Furthermore, the specification does not teach the sequence of the 56-58 amino acid repeated motif, except for an improper incorporation by reference to a printed publication.

Since the specification contains conflicting definitions of "an ADC nucleic acid", and some of the definitions are so broad as to encompass virtually anything affecting seed properties, the intended metes and bounds of the claimed subject matter are very unclear.

Furthermore, claims 5, 15, 26, 36, and 41 are unclear because they refer to Genbank accession numbers rather than to sequences set forth in the specification. This is seen as an improper incorporation by reference, since the information required to describe and enable the

required sequences is found in the Genbank database, extraneous to the application. Furthermore, since Genbank sequences are not irrevocably fixed but are corrected and updated as additional sequence information becomes available, the Genbank accession number may refer to sequences which change after the application filing date. The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973). Furthermore, if a required sequence was not set forth in the specification as filed, and was not publicly available from Genbank at the time the application was filed, the amendment will be treated as an attempt to introduce new matter (similar to attempts to incorporate essential material by reference to unpublished material).

In addition, claim 44 is unclear, since a nucleic acid cannot be a member of the genus Brassica.

Claims 1-44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the

invention. The scope of the claims is so indefinite that one skilled in the art cannot practice the full scope of the invention, simply because it is impossible to make or use the full scope of an invention when one cannot even define the full scope of the invention.

Furthermore, it is noted that Tables VI and VII in the specification show considerable variation in seed mass and fatty acid composition in wild type plants (compare C24 in table VI with COL in table VII), and also show considerable variation in individual plants made using the same recombinant DNA. Still further, it is clear from the specification that plant genomes contain many different sequences related to AP2, which are expressed in different tissues at different times. Therefore there is reason to believe that the different sequences have different phenotypic effects in plants, and reason to doubt unsupported assertions that all sequences with some structural similarity can be used to influence seed properties, and reason to believe that the outcome is unpredictable. Considering the limited scope of working examples, and the variation in results achieved in the working examples and even in the controls, it is concluded that undue experimentation would be required to practice the full scope of the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 35, 36, 38, 39, 40, 41, 43 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Jofuku et al (The Plant Cell 6: 1211-1225), see page 1215, first paragraph.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is (703) 308-2926. The examiner can normally be reached on Monday -Thursday and alternate Fridays from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marian Knode, can be reached on (703) 308-4311. The fax phone number for this Group is now (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196 .

June 22, 1998

MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800
1600